

**SECTION 5: Special 510(k) Summary of Safety and Effectiveness****A. Device Information:**

Category	Comments
Sponsor:	Endoscopic Technologies, Inc., (dba Estech) 2603 Camino Ramon Suite 100 San Ramon, CA 94583 Tel: 925-543-2110
Correspondent:	Tamer Ibrahim Vice President ESTECH, Inc
Contact Information:	Tel: 925-543-2110 Fax: 925-866-7117
Device Common Name:	Electrosurgical cutting and coagulation device and accessories
Device Proprietary Name:	Estech COBRA® Genesis Bipolar Clamp
Device Classification:	Class II, GEI (21 CFR 878.4400)

**Predicate Device Information:**

Predicate Devices:	Estech COBRA Bipolar System II (K100224)
Predicate Device Manufacturers:	Endoscopic Technologies, Inc (dba Estech)
Predicate Device Common Name:	Electrosurgical cutting and coagulation device and accessories
Predicate Device Classification:	21 CFR 878.4400
Predicate Device Classification Number:	Class II, GEI

**B. Date Summary Prepared**

25 September 2013

**C. Description of Device**

The Estech COBRA® Genesis Bipolar Clamp is a sterile, single-use device designed to guide RF energy to the target tissue via electrodes in the jaws of a surgical clamp style device. RF energy is delivered in a bipolar mode, with one jaw of the device as the ablative electrode and the other jaw as the indifferent electrode.

**D. Intended Use**

*The Estech COBRA® Genesis Bipolar Clamp is intended for the coagulation of soft tissue during general surgery. The system may also be used to coagulate blood and soft tissue to produce hemostasis.*

#### **E. Comparison to Predicate Device**

The Estech COBRA® Genesis Bipolar Clamp is identical in indications for use, technology, manufacturing, packaging and sterilization to the predicate ESTECH Cobra Bipolar II System (K100224).

There are minor design differences between the application and predicate devices. These design differences (non-rotatable jaws, single active electrode) provide improved stability and ease of use for the physician, but do not alter the performance profile seen in the predicate device.

#### **F. Summary of Supporting Data**

The testing supplied in Section 18 demonstrates that the joints and other mechanical aspects of the design of the Estech COBRA® Genesis Bipolar Clamp are adequate for use. Additionally, the data demonstrates that the ablation performance of the Estech COBRA® Genesis Bipolar Clamp is equivalent to that of the predicate.

The patient contacting materials of the Estech COBRA® Genesis Bipolar Clamp have been demonstrated to be bio-compatible, in accordance with ISO 10993: Biological Evaluation of Medical Devices, and the safety of the electrical design is in conformance with the pertinent sections of IEC 60601-2-2: Medical electrical equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment (see reference test reports in Sections 15 and 17).

#### **G. Summary of Supporting Data**

Estech concludes that the Estech COBRA® Genesis Bipolar Clamp is substantially equivalent to the predicate ESTECH Cobra Bipolar II System (K100224). The indications for use, technology, manufacturing, materials, packaging, and sterilization methods are identical to that of the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

Endoscopic Technologies, Incorporated, dba Estech  
Mr. Tamer Ibrahim  
Vice President, R&D/RA/QA  
2603 Camino Ramon, Suite 100  
San Ramon, California 94583

October 7, 2013

Re: K133017

Trade/Device Name: Estech COBRA<sup>®</sup> Genesis Bipolar Clamp  
Regulation Number: 21 CFR 878.4400  
Regulation Name: Electrosurgical cutting and coagulation device and accessories  
Regulatory Class: Class II  
Product Code: GEI  
Dated: September 25, 2013  
Received: September 26, 2013

Dear Mr. Ibrahim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Mark N. Melkerson -S**

Mark N. Melkerson  
Acting Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

#### SECTION 4: Indications for Use

510(k) Number (if known): K133017

Device Name: Estech COBRA® Genesis Bipolar Clamp

Indications for Use:

*The Estech COBRA® Genesis Bipolar Clamp is intended for the coagulation of soft tissue during general surgery. The system may also be used to coagulate blood and soft tissue to produce hemostasis.*

Prescription Use  X

AND/OR

Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H.  
Chen -A

Digitally signed by Long H. Chen -A  
DN: cn=US, o=U.S. Government, ou=FDA,  
ou=FDA, ou=People, cn=Long H. Chen -A  
c=US  
Date: 2013.10.07 07:22:50 -0400

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for MXM

(Division Sign-Off)

Division of Surgical Devices

510(k) Number: K133017